

The opinion in support of the decision being entered today was **not** written for publication in a law journal and is **not** binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID E. BUTTERWORTH

Appeal No. 1998-2029
Application No. 08/258,643

ON BRIEF

Before CALVERT, NASE, and GONZALES, Administrative Patent Judges.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the refusal of the examiner to allow claims 1-11.¹ These claims constitute all of the claims pending in this application.

We AFFIRM-IN-PART.

¹ Claim 10 was amended subsequent to the final rejection.

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BACKGROUND

The appellant's invention relates to a drape that includes a sealable pouch to collect runoff from a surgical site (specification, p. 1). A copy of claims 1-9 and 11 under appeal is set forth in the appendix to the appellant's brief (Paper No. 13, filed August 31, 1995). A copy of claim 10 under appeal is set forth in the appellant's reply (Paper No. 18, filed November 6, 1996).

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Staller 1968	3,416,585	Dec. 17,
Morris et al. (Morris) 1984	4,489,720	Dec. 25,
Idris 1989	4,869,271	Sep. 26,

Claims 1, 2, 4-8, 10 and 11 stand rejected under 35 U.S.C.
§ 103 as being unpatentable over Idris in view of Morris.

Claims 3 and 9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Idris in view of Morris as applied to claims 1 and 7 above, and further in view of Staller.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the answer (Paper No. 17, mailed September 3, 1996) and the supplemental answer (Paper No. 19, mailed December 11, 1996) for the examiner's complete reasoning in support of the rejections, and to the brief and reply for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

Claims 7-9

We will not sustain the rejection of claims 7-9 under 35 U.S.C. § 103.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established by presenting evidence that would have led one of ordinary skill in the art to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) and In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Claims 7-9 recite a disposable surgical drape comprising, inter alia, a sheet having a fenestration and a pouch having (1) a thermoplastic layer having an opening defined by an inner perimetric edge and an outer perimetric edge secured to the sheet in a liquid tight seal that completely surrounds the fenestration, and (2) closure means for sealing the inner

perimetric edge to the sheet to close the pouch in a fluid tight manner.

The appellant argues (brief, p. 10) that the applied prior art does not teach the limitation that the pouch has a thermoplastic layer sealed to the sheet about a perimetric edge which completely surrounds the fenestration as set forth in independent claim 7. The examiner did not respond to this argument.

After reviewing the teachings of the applied prior art (i.e., Idris, Morris and Staller), we find ourselves in agreement with the appellant that the applied prior art does not teach the limitation that the pouch has a thermoplastic layer sealed to the sheet about a perimetric edge which completely surrounds the fenestration as set forth in independent claim 7.² Thus, the applied prior art does not

² The appellant appears to have admitted (specification, p. 9) that drapes that meet this limitation are described in U.S. Patent No. 5,161,544 (the subject matter of this patent appears to have been published on September 18, 1991 as European Patent Application 0 447 217 A1 and therefore would
(continued...)

suggest the invention set forth in claims 7-9. Accordingly, the decision of the examiner to reject claims 7-9 under 35 U.S.C. § 103 is reversed.

Claims 1, 2, 4-6, 10 and 11

We sustain the rejection of claims 1, 2, 4-6, 10 and 11 under 35 U.S.C. § 103.

Idris discloses a fenestrated surgical drape which has a fluid collection pouch pivotally attached about the fenestration so that the pouch may be selectively attached to either side of the fenestration. As shown in Figures 1-3, a drape or mainsheet 10 includes a top edge 12 and a bottom edge 14 joined by a pair of opposed side edges 16 and 18 thereby defining a top surface 20 and a bottom surface 22 with a fenestration 24 located interiorly therein. Pivotaly attached to the top surface 20 of the drape 10 is a fluid collection pouch 26. The fluid collection pouch 26 is formed

²(...continued)
constitute 35 U.S.C. § 102(b) type prior art to this application).

from a first sheet 28 and a second sheet 30 having commonly joined side edges with open top edges 28a and 30a thereby defining a fluid receiving chamber 32. Each of the top edges 28a and 30a is cut out inwardly toward the bottom of the pouch 26 such that they will not overlap the fenestration 24. The junctures of the top edges 28a and 30a and side edges are permanently secured to the top surface 20 of the drape 10 by securing means 34 such as adhesive tape, hot melt adhesive or heat sealed joints, for example.

Idris teaches that the attachment of the pouch 26 to the drape 10 should be in such a fashion that the pouch can be selectively pivoted about the secured area to either side of the fenestration 24 as shown by the arrow 36 in Figure 2. In either position, it can be seen that the open top edges 28a, 30a of the pouch 26 do not interfere with or overlap the fenestration 24. Idris further teaches that to keep the pouch open to receive fluids, the first and second sheets 28 and 30 may be fitted with malleable strips 42 adjacent the respective top edges 28a and 30a. Idris also teaches that the fluid collection pouch 26 may be fitted with a drain fitting 44

adjacent the lowermost position of the fluid receiving chamber 32 to allow for the drainage of collected fluids from the pouch 26. Idris discloses that most typically the drain fitting 44 is connected to flexible tubing (not shown) which is fed into a fluid receptacle such as a bucket (not shown) to collect the drained fluids.

Morris discloses a surgical drape for use in cesarean section procedures. As shown in Figures 1-6, the drape 10 includes a fenestration 33 and has a fluid collection bag 19 secured to the lower surface of the drape to collect amniotic and other fluids released during the surgery. The fluid collection bag 19 is maintained in an open position by a moldable strip 25 at the opening of the bag. In addition, fluid direction flaps 17 are inserted into the opening 21 of the bag 19. Morris teaches (column 3, line 64, to column 4, line 5) that

[t]he upper, top edge of the fluid collection bag which is on the upper surface of the drape forms a flap 22 and has an adhesive, preferably a double-faced adhesive tape 23 on its surface. There is a release sheet 24 over the outer surface of the tape. This flap 22 is folded away from the opening 21. The purpose of the adhesive surface is to allow the collection bag to be

sealed after the completion of the surgical procedure so that the fluid will not escape from the bag as the drape is being removed from the patient.

Morris further discloses that there may be a drainage tube 35 in the lower, closed end of the bag 19 to drain excess fluid from the bag 19. Morris further teaches (column 4, lines 18-41) that

[t]he drape is folded into a compact size to allow the drape to be aseptically placed in position on the patient. The drape is preferably folded so that the incise film 16 is on the outer surface of the folded drape. When placing the drape on the patient, the release sheet 26 is removed from the adhesive surface of the film 16, and the film is secured to the skin of the patient over the operative site. The drape is then unfolded and spread over the patient's body. After the drape is unfolded, the paper insert 27, covering the upper surface of the film 16, is removed and discarded. The initial surgical incision is made through the fenestration 33 in the film. The metal strip 25 is then bent in an appropriate shape to insure the opening 21 is maintained in communication with the fluid collection bag 19. The bag 19 may be conveniently placed between the patient's legs, out of the way of the surgical staff. Any fluid from the site of the incision is directed by the flaps 17 through the opening 21 in the drape and into the fluid collection bag 19. When the surgical incision is to be closed, the release sheet 24 on the flap 22 of the bag is removed, and the flap 22 is secured to the upper surface of the drape, sealing the fluid collection bag.

After the scope and content of the prior art are determined, the differences between the prior art and the claims at issue are to be ascertained. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

The examiner ascertained (answer, pp. 5 & 6) that the only difference between Idris and claims 1, 2, 4-6, 10 and 11 was that Idris lacked means for detachably sealing the top edge of the pouch 26 (e.g., the closure means of claim 1; the sealing step of claim 10). The examiner then determined that it would have been obvious to one of ordinary skill in the art to take the teachings of Morris (i.e., to seal the fluid collection bag) and apply them to the disclosed device of Idris, in order to prevent contamination of the patient as suggested implicitly by Morris. We agree.

The appellant argues that neither Idris or Morris suggests a device having a pouch capable of being sealed in a fluid tight manner to allow disposal of the drape. We do not agree.

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Moreover, in evaluating such references it is proper to take into account not only the specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). Moreover, skill is presumed on the part of those practicing in the art. See In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

It is our opinion that Morris suggests a device having a pouch capable of being sealed in a fluid tight manner to allow disposal of the drape. In that regard, Morris teaches that the purpose of the adhesive surface is to allow the fluid collection bag to be sealed after the completion of the surgical procedure so that the fluid will not escape from the bag as the drape is being removed from the patient. The appellant's position that the drawings of Morris indicate that

his fluid collection bag does not form a complete fluid tight seal when the fluid collection bag is sealed by the adhesive tape is speculation unsupported by any evidence³ and directly contrary to the specific teachings of Morris that the fluid collection bag is sealed. In our view, the combined teachings of the applied prior art would have made it obvious at the time the invention was made to a person having ordinary skill in the art to have provided Idris's pouch with a closure means for sealing the pouch in a fluid tight manner.

For the reasons set forth above, the decision of the examiner to reject claims 1, 2, 4-6, 10 and 11 under 35 U.S.C. § 103 is affirmed.

Claim 3

We sustain the rejection of claim 3 under 35 U.S.C. § 103.

³ Attorney's argument in a brief cannot take the place of evidence. In re Pearson, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974).

Claim 3 adds to parent claim 1 the further limitation that the closure means is "an interlocking ridge- and channel-structure."

Staller discloses a flexible container having interlocking rib and groove closure elements. Staller teaches (column 1, lines 15-20) that plastic or plastic-like flexible containers having reclosable elements offer a plurality of advantages over other containers.

In applying the above-noted test for obviousness, we reach the conclusion that it would have been obvious at the time the invention was made to a person having ordinary skill in the art to have sealed the collection pouch of Idris as suggested by the teachings of Morris by utilizing interlocking rib and groove closure elements as taught by Staller.

The appellant argues in addition to the argument set forth above with respect to claim 1 that there is no suggestion to combine the applied prior art to arrive at the claimed invention. We do not agree. In our view, the applied

prior art of Morris and Staller clearly would have suggested to a person having ordinary skill in the art that adhesive and interlocking rib and groove closure elements were known sealing alternatives at the time the invention was made. Accordingly, the substitution of interlocking rib and groove closure elements for an adhesive seal would have been obvious at the time the invention was made to a person having ordinary skill in the art.

For the reasons set forth above, the decision of the examiner to reject claim 3 under 35 U.S.C. § 103 is affirmed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1-6, 10 and 11 under 35 U.S.C. § 103 is affirmed and the decision of the examiner to reject claims 7-9 under 35 U.S.C. § 103 is reversed.

No time period for taking any subsequent action in
connection with this appeal may be extended under 37 CFR
§ 1.136(a).

AFFIRMED-IN-PART

IAN A. CALVERT)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
JEFFREY V. NASE)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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